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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,860	03/31/2004	Paul Barry	P03464	5584
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Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			PARK, EDWARD	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/813,860	BARRY ET AL.
	Examiner	Art Unit
	Edward Park	2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 July 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 5-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is responsive to applicant's amendment and remarks received on 7/11/07. Claims 1-3, 5-10 are currently pending.

Claim Objections

2. In response to applicant's cancellation of claim 4, the previous claim objection is withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. **Claims 1-3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sites et al (US 5,515,159) in view of Krahn et al (US 6,757,420 B2).

Regarding **claim 1**, Sites teaches a method of inspecting the seal area between a blister package and a cover, said method comprising the steps of:

- a) providing an image pick-up device (Sites: figure 1, numeral 36-1, 36-2);

b) presenting the blister package with cover adhered thereto to the field of view of said image pick-up device (Sites: figure 9, numeral 130);

c) imaging and determining the grey level of said seal area and comparing the imaged grey level to a predetermined grey level value (Sites: col. 7, lines 46-67; col. 8, lines 1-17); and

d) passing the blister package inspection if the imaged grey level is substantially the same as the predetermined grey level value or rejecting the blister package inspection if the imaged grey level is not substantially the same as the predetermined grey level value (Sites: figure 9, numeral 150). Sites does not teach wherein the blister package contains an ophthalmic lens in solution.

Krahn teaches wherein the blister package contains an ophthalmic lens in solution (“disposable contact lenses, are sealed into blister packages ... to which isotonic sodium chloride solution (saline) is also added”; Krahn: col. 1, lines 21-41).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Sites reference to utilize the inspection method on ophthalmic lens in solution as suggested by Krahn, to enhance the reliability of the blister packages that contain ophthalmic lens in solution by detecting any defects before distribution to consumers.

Regarding **claim 2**, Sites teaches projecting a series of ROIs on the imaged seal area and wherein imaging of the grey level of the seal area occurs within each ROI (Sites: figure 5; figure 9, numeral 134).

Regarding **claim 3**, Sites teaches calculating the size of an imaged grey level that is not the same as the predetermined grey level value and passing the blister package inspection if the size is substantially the same or smaller than a predetermined acceptable size or rejecting the

blister package inspection if the size is greater than the predetermined acceptable size (Sites: col. 2, lines 14-26).

5. **Claims 5, 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sites et al (US 5,515,159) with Krahn et al (US 6,757,420 B2), and further in view of Schwartz et al (US 6,252,980 B1).

Regarding **claims 5 and 8**, Sites with Krahn combination discloses all elements as mentioned above in claim 1. Sites with Krahn combination does not teach imaging the fill level of solution held in the blister package and comparing the imaged fill level with a predetermined acceptable fill level and passing the blister package if the imaged fill level is substantially the same as the predetermined accepted fill level or rejecting the blister package if the imaged fill level is less than the predetermined acceptable fill level, and a blister package that is oriented vertically during said inspection.

Schwartz teaches imaging the fill level of solution held in the blister package and comparing the imaged fill level with a predetermined acceptable fill level (Schwartz: col. 3, lines 59-67; col. 4, lines 1-5) and passing the blister package if the imaged fill level is substantially the same as the predetermined accepted fill level or rejecting the blister package if the imaged fill level is less than the predetermined acceptable fill level (Schwartz: col. 4, lines 25-34), and a blister package that is oriented vertically during said inspection (Schwartz: figure 2, numeral 209).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Sites with Krahn combination to compare fill levels and vertically inspect

the blister package as suggested by Schwartz, to ensure that the proper amount of solution/liquid is within the blister packages before distribution to consumers.

6. **Claims 6-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sites et al (US 5,515,159) with Schwartz et al (US 6,252,980 B1), and further in view of Krahn et al (US 6,757,420 B2).

Regarding **claim 6**, Sites teaches a method of inspecting the fill level of a solution in a sealed blister package, said method comprising the steps of providing an image pick-up device (Sites: figure 1, numeral 36-1, 36-2) and presenting the blister package to the field of view of said image pick-up device (Sites: figure 9, numeral 130).

Sites does not teach imaging and determining the fill level of the solution within the blister package and comparing the imaged fill level to a predetermined fill level value; passing the blister package inspection if the imaged fill level is substantially the same as the predetermined fill level value or rejecting the blister package inspection if the imaged fill level is not substantially the same as the predetermined fill level value and wherein the blister package contains an ophthalmic lens in solution.

Schwartz teaches:

imaging and determining the fill level of the solution within the blister package and comparing the imaged fill level to a predetermined fill level value (Schwartz: col. 3, lines 59-67; col. 4, lines 1-5); passing the blister package inspection if the imaged fill level is substantially the same as the predetermined fill level value or rejecting the blister package inspection if the imaged fill level is not substantially the same as the predetermined fill level value (Schwartz: col. 4, lines 25-34).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Sites reference to image and determine the fill level as suggested by Schwartz, to ensure that the proper amount of solution/liquid is within the blister packages before distribution to consumers.

Krahn teaches a blister package that contains an ophthalmic lens in solution (“disposable contact lenses, are sealed into blister packages ... to which isotonic sodium chloride solution (saline) is also added”; Krahn: col. 1, lines 21-41).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Sites with Schwartz combination to utilize the inspection method on ophthalmic lens in solution as suggested by Krahn, to ensure that the proper amount of solution/liquid is within the blister packages that contain ophthalmic lens in solution before distribution to consumers.

Regarding **claim 7**, Sites, Schwartz, with Krahn combination discloses all elements as mentioned above in claim 6. Sites, Schwartz, with Krahn combination does not teach a blister package that is oriented vertically with respect to said image pick-up device.

Schwartz further teaches blister package is oriented vertically with respect to said image pick-up device (Schwartz: figure 2, numeral 209).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Sites, Schwartz, with Krahn combination to vertically orient the blister package as suggested by Krahn, to ensure that the proper amount of solution/liquid is within the blister packages before distribution to consumers.

7. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Krahn et al (US 6,757,420 B2) with Sites et al (US 5,515,159) and further in view of Ebel et al (US 5,568,715).

Regarding **claim 9**, Krahn teaches placing an ophthalmic contact lens and a packaging solution in a well of a blister package (“disposable contact lenses, are sealed into blister packages”; Krahn: col. 1, lines 23-24), and adhering lidstock to an upper side of the blister package around the well (Krahn: col. 1, lines 8-20), the lidstock comprising a base layer which bonds to the blister package around the well by application of heat and pressure, and an upper foil layer (Krahn: col. 1, lines 8-20). Krahn does not teach providing an image pick-up device; presenting an underside of the blister package with the lidstock adhered thereto to the field of view of said image pick-up device; imaging and determining the grey level of said seal area and comparing the imaged grey level to a predetermined grey level value; and passing the blister package inspection if the imaged grey level is substantially the same as the predetermined grey level value or rejecting the blister package inspection if the imaged grey level is not substantially the same as the predetermined grey level value.

Sites teaches providing an image pick-up device (Sites: figure 1, numeral 36-1, 36-2); imaging and determining the grey level of said seal area and comparing the imaged grey level to a predetermined grey level value (Sites: col. 7, lines 46-67; col. 8, lines 1-17); and passing the blister package inspection if the imaged grey level is substantially the same as the predetermined grey level value or rejecting the blister package inspection if the imaged grey level is not substantially the same as the predetermined grey level value (Sites: figure 9, numeral 150).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Krahn reference to image, determine, grey level, and evaluate blister package as suggested by Sites, to “determine the existence of any defects” (Sites: col. 1, lines 20) that will compromise the integrity of the blister packages before distribution to consumers.

Ebel teaches presenting an underside of the blister package with the lidstock adhered thereto to the field of view of said image pick-up device (figure 12, Ebel: col. 6, lines 25-41).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Krahn with Sites combination to image the underside of the blister package as suggested by Ebel, to physically retrieve image data for inspection and analysis, which would not be possible if the blister package was presented in any other way due to upper-side of the package being metallic and non-transparent.

8. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Krahn et al (US 6,757,420 B2), Sites et al (US 5,515,159), with Ebel et al (US 5,568,715), and further in view of Schwartz et al (US 6,252,980 B1).

Regarding **claim 10**, Krahn, Sites, with Ebel combination discloses all elements as mentioned above in claim 9. Krahn, Sites, with Ebel combination does not teach imaging the fill level of solution held in the blister package and comparing the imaged fill level with a predetermined acceptable fill level and passing the blister package if the imaged fill level is substantially the same as the predetermined accepted fill level or rejecting the blister package if the imaged fill level is less than the predetermined acceptable fill level.

Schwartz teaches imaging the fill level of solution held in the blister package and comparing the imaged fill level with a predetermined acceptable fill level (Schwartz: col. 3, lines

59-67; col. 4, lines 1-5) and passing the blister package if the imaged fill level is substantially the same as the predetermined accepted fill level or rejecting the blister package if the imaged fill level is less than the predetermined acceptable fill level (Schwartz; col. 4, lines 25-34).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the Krahn, Sites, with Ebel combination to compare fill levels as suggested by Schwartz, to ensure that the proper amount of solution/liquid is within the blister packages before distribution to consumers.

Response to Arguments

9. Applicant's arguments with respect to **claim 1** have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, **claims 5-7**, applicant argues that one skilled in the art would not combine Sites et al with Schwartz et al in regards to the measurement of fluid height. This argument is not considered persuasive since only the concept of measuring the fluid is taken from the Schwartz reference and combined with Sites. Sites does not have to disclose or suggest packages

containing any type of fluid since Schwartz brings in the concept of measuring fluid level as a secondary teaching.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Park whose telephone number is (571) 270-1576. The examiner can normally be reached on M-F 09:00-17:00, (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Edward Park
Examiner
Art Unit 2609

/Edward Park/

/Brian P. Werner/
Supervisory Patent Examiner (SPE), Art Unit 2624